TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER d: LABORATORIES AND BLOOD BANKS

PART 450
ILLINOIS CLINICAL LABORATORIES CODE

SUBPART A: GENERAL

Section

SUBPART B: DIRECTORS OF CLINICAL LABORATORIES

Section

SUBPART C: LOCATION, CONSTRUCTION AND SANITATION

Section

SUBPART D: QUALIFICATIONS OF PERSONNEL

Section

SUBPART E: EQUIPMENT

Section

SUBPART F: OUT OF STATE LABORATORIES

Section

SUBPART G: PROFICIENCY SURVEY PROGRAM AND INSPECTION OF FACILITIES

Section

SUBPART H: SPECIAL REQUIREMENTS PERTAINING TO BLOOD BANKS ~~(Repealed)~~

Section

SUBPART I: PROHIBITED PRACTICE

Section

SUBPART J: RECORDS AND REPORTS

SUBPART K: QUALITY CONTROL

SUBPART L: HIV CONTAMINATED BLOOD AND HUMAN TISSUE

SUBPART M: HEALTH SCREENING

AUTHORITY: Implementing and authorized by the Illinois Clinical Laboratory and Blood Bank Act [210 ILCS 25].

SOURCE: Amended November 16, 1970; amended at 2 Ill. Reg., p. 87, effective November 5, 1978; amended at 4 Ill. Reg. 33, p. 224, 225 and 228, effective August 6, 1980; amended at 6 Ill.

Reg. 4151, effective April 5, 1982; amended at 7 Ill. Reg. 7643, effective June 14, 1983; codified at 8 Ill. Reg. 19488; amended at 9 Ill. Reg. 20709, effective January 3, 1986; emergency amendment at 10 Ill. Reg. 307, effective January 3, 1986, for a maximum of 150 days; amended at 10 Ill. Reg. 10712, effective June 3, 1986; amended at 12 Ill. Reg. 10018, effective May 27, 1988; emergency amendment at 12 Ill. Reg. 19518, effective October 28, 1988, for a maximum of 150 days; amended at 13 Ill. Reg. 4285, effective March 21, 1989; amended at 13 Ill. Reg. 11573, effective July 1, 1989 and September 1, 1989; emergency amendment at 13 Ill. Reg. 13678, effective August 14, 1989, for a maximum of 150 days; emergency rule expired January 11, 1990; amended at 14 Ill. Reg. 2360, effective January 26, 1990; amended at 15 Ill. Reg. 15727, effective October 18, 1991; amended at 44 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL

Section 450.5 Scope and Applicability

a) This Part provides regulatory oversight~~The major thrust of this regulatory scheme is to require some form of regulation~~ of all entities, licensed (certified) pursuant to 42 CFR 493, that perform analysis of human specimens for health assessment or to diagnose, prevent or treat disease.~~under the following five stage classification scheme:~~

~~1) Exempt Laboratory;~~

~~2) Class I Permit Laboratory;~~

~~3) Class II Permit Laboratory;~~

~~4) Class III Permit Laboratory;~~

~~5) Licensed Laboratory.~~

b) All certified CLIA laboratories will be regulated~~ as one of these five levels of classification~~ as set forth in 42 CFR 493 and described in the State Operations Manual (Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services), issued by the Department of Health and Human Services~~depending upon the tests they conduct, the source of the specimens, and organizational structure. Each of these levels, except exempt laboratories, has regulatory requirements concerning the qualifications of the laboratory director, qualifications of laboratory personnel, proficiency testing and quality control as set forth in this Part. (See Appendix C)~~.

~~1) Exempt Laboratory~~

~~A)~~ ~~In order to qualify as an exempt laboratory, the laboratory must meet the definition of a "Class I Permit" laboratory and only conduct those tests specified in the regulations. As set forth in the Illinois Clinical Laboratory Act (Ill. Rev. Stat. 1989 and 1990 Supp., ch. 111½, par. 621 et seq.) ("the Act") and this Part, an exempt laboratory can be any "single practice of medicine, podiatry or dentistry" which owns and operates a laboratory exclusively for its patients, or a local health authority or designated agency which owns and operates a laboratory for its own clients or patients, at stated locations when testing is limited to tests which are set forth in Section 450.35(a).~~

~~B)~~ ~~If an exempt laboratory conducts tests other than those listed it must seek another level of classification. Furthermore, health screening activities under Section 1-103 and 2-120 of the Act may be conducted by laboratories at locations other than the location or locations set forth in the permit or licensure application, however such health screenings must be conducted in accordance with Sections 450.1300, 450.1310, 450.1320, and 450.1330. An Exempt Laboratory is not exempt from the provisions of this Part concerning health screening.~~

~~C)~~ ~~The Department expects physicians, podiatrists, dentists, local health authorities, and designated agencies to qualify as exempt laboratories.~~

~~2)~~ ~~Class I Laboratory~~

~~A)~~ ~~As set forth in this Part, a "Class I Permit" laboratory can be any "single practice of medicine, podiatry or dentistry" which owns and operates a laboratory exclusively for its patients or a local health authority or designated agency which owns and operates a laboratory for its own clients or patients at stated locations when testing is limited to simple tests and those tests or categories of tests set forth by regulations as defined of this Part. Some or all testing may be done by a laboratory assistant under the direction of the physician, podiatrist or dentist.~~

~~B)~~ ~~The "Class I Permit" laboratory must obtain a permit annually from the Department. Generally, the other major requirements are as follows:~~

~~i)~~ ~~the minimum level for the qualifications of the laboratory~~

director include any physician (M.D., D.O., or D.C.), dentist, podiatrist, or person with at least a master's degree with a major in chemical or biological sciences.

ii) the minimum level for the qualifications of laboratory personnel include a laboratory assistant. Section 450.450 of this Part specifies that a laboratory assistant is any person who meets the education and experience requirements set by the laboratory director.

iii) the minimum level of proficiency testing requires proficiency testing for all tests conducted by the laboratory when available from an approved proficiency testing service.

iv) the minimum level of quality control requires such testing for all tests conducted by the laboratory.

C) The Department expects physicians, podiatrists, dentists, local health authorities, and designated agencies to seek "Class I Permit" Laboratory status. Health screening activities under Section 1-103 and 2-120 of the Act may be conducted by class I laboratories at locations other than the location or locations set forth in the permit or licensure application, however such health screenings must be conducted in accordance with Sections 450.1300, 450.1310, 450.1320, and 450.1330 of this Part.

3) Class II Laboratory

A) As set forth in this Part, a "Class II Permit" laboratory can be any laboratory at a stated location operated and maintained exclusively for the patients of physicians, podiatrists or dentists at that location and who own the laboratory or are employed by the owner, or a local health authority or designated agency which owns and operates a laboratory for its own clients or patients or for clients or patients of other local health authorities or designated agencies at stated locations.

B) The "Class II Permit" laboratory must obtain a permit annually from the Department. Generally, the other major requirements are as follows:

i) the minimum level for the qualifications of the laboratory

director includes a physician licensed to practice medicine in all of its branches, or a person with at least a master's degree with a major in chemical or biological sciences.

ii) the minimum level for the qualifications of laboratory personnel includes a laboratory technician. Section 450.440 of this Part specifies that a laboratory technician is any person who completes at least 60 hours of academic credit including chemistry and biology, a high school graduate who has completed a 1-year accredited training program, or a high school graduate who has completed an official military medical laboratory procedures course of at least 50 weeks.

iii) the minimum level of proficiency testing requires proficiency testing for all tests conducted by the laboratory.

iv) the minimum level of quality control requires such testing for all tests conducted by the laboratory.

C) The Department expects physicians, local health authorities, and designated agencies to seek "Class II Permit" laboratory status. Health screening activities under Section 1-103 and 2-120 may be conducted by class II laboratories at locations other than the location or locations set forth in the permit or licensure application, however such health screenings must be conducted in accordance with Sections 450.1300, 450.1310, 450.1320, and 450.1330.

4) Class III Laboratory

A) As set forth in this Part, a "Class III Permit" laboratory can be any laboratory which is operated and maintained exclusively for the purposes of conducting health screening tests by a person, corporation, organization, association or group directly or indirectly on a for profit basis. The health screening tests are listed as glucose and cholesterol by fingerstick in this Part.

B) The "Class III Permit" laboratory must obtain a permit annually from the Department and must comply with Sections 450.1300, 450.1310, 450.1320, and 450.1330. The "Class III Permit" laboratory has no other regulatory requirements. Generally, the other major requirements are as follows:

~~i) the minimum level for the qualifications of the laboratory director include a physician licensed to practice medicine in all of its branches, or a person with at least a master's degree with a major in chemical or biological sciences.~~

~~ii) the minimum level for the qualifications of laboratory personnel include a laboratory assistant or laboratory technician. Section 450.450 of this Part specifies that a laboratory assistant is any person who meets the education and experience requirements set by the laboratory director. Section 450.440 of this Part specifies that a laboratory technician is any person who completes at least 60 hours of academic credit including chemistry and biology, a high school graduate who has completed a 1 year accredited training program, or a high school graduate who has completed an official military medical laboratory procedures course of at least 50 weeks.~~

~~iii) the minimum level of proficiency testing requires proficiency testing for all tests conducted by the laboratory.~~

~~iv) the minimum level of quality control requires such testing for all tests conducted by the laboratory.~~

~~C) The Department expects corporations and groups to seek "Class III Permit" laboratory status.~~

c~~5~~) Licensed (Certified) Laboratory

1~~A~~) As set forth in this Part, a "licensed~~Licensed~~" laboratory is a~~can be any~~ laboratory certified by the Department under the standards set forth in CLIA laws and regulations (CLIA Law) to accept and test clinical human~~at a stated location regardless of ownership which accepts~~ specimens from a person, ~~authorized by law~~ in accordance with Article VII of the Act~~to submit such specimens when testing is limited to that which is within the qualifications of the Director as set forth in this Part~~.

2~~B~~) The licensed~~"Licensed"~~ laboratory shall maintain certification status in good standing as required by CLIA Law.~~must obtain a license annually from the Department. Generally the other major requirements are as follows:~~

~~i) the minimum level for the qualifications of the laboratory~~

~~director includes a physician licensed to practice medicine in all its branches who is Board certified or eligible or who possesses acceptable qualifications as set forth in this Part, or a person with at least a master's degree with a major in chemical or biological sciences.~~

~~ii)~~ ~~the minimum level for the qualifications of laboratory personnel include a general supervisor. Section 450.410 of this Part specifies that a general supervisor may be any physician with additional qualifications, a medical technologist, a person with a master's degree in medical laboratory science or other similarly qualified individuals.~~

~~iii)~~ ~~the minimum level of proficiency testing requires proficiency testing for all tests conducted by the laboratory.~~

~~iv)~~ ~~the minimum level of quality control requires such testing for all tests conducted by the laboratory.~~

d~~C~~) Physicians~~The Department expects physicians~~, corporations, individuals, local health authorities, and others that intend to conduct clinical tests on human specimens for health assessments or to diagnose, prevent or treat disease shall obtain certification status by the Department in accordance with CLIA Law~~to seek "Licensed" Laboratory status~~. Health screening activities under Section ~~1-103 and~~ 2-120 of the Act may be conducted by a certified~~licensed~~ laboratory at its certificate address locations; ~~other than the location or locations set forth in the permit or licensure application,~~ however, ~~such~~ health screening~~screenings~~ events shall~~must~~ be conducted in accordance with Sections 450.1300, 450.1310, ~~450.1320,~~ and 450.1330.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.10 Definitions

~~"Accredited Institution" or "Accredited College or University" means a college or university located in the United States which has been accredited by one of the regional accreditation programs recognized by the U.S. Office of Education or a college or university located outside the United States where the individual provides documentation that his/her education is equivalent to that provided in the United States by: documenting that the foreign degree has been accepted by an accredited institution in the United States at which the person is or was enrolled in a graduate program; or having his/her credentials evaluated by the Credentials Evaluation Service, Inc., Los Angeles, California.~~

"Act" or "Clinical Laboratory Act" – ~~means~~ the Illinois Clinical Laboratory and Blood Bank Act~~Illinois Clinical Laboratory Act (Ill. Rev. Stat. 1987, ch. 111½, par. 621 et seq., as amended by P.A. 85-1025, effective June 30, 1988; P.A. 85-1202, effective August 25, 1988, and P.A. 85-1251 effective August 30, 1988.)~~.

"Approved Clinical Laboratory" – a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988~~means a clinical laboratory (with a director at the doctoral level) of a hospital, health department, university, or medical research institution; or a clinical laboratory having a license or class II permit under the Illinois Clinical Laboratory Act; or a blood bank licensed under the Blood Bank Act; or a clinical laboratory licensed under the Clinical Laboratories Improvement Act of 1967; or, a clinical laboratory approved under 42 CFR 405, Subpart M effective September 30, 1977~~.

~~"Blood Bank Act" means the Illinois Blood Bank Act, (Ill. Rev. Stat. 1987, ch. 111½, pars. 601-101 et seq.)~~

~~*"Class I Permit" means a permit issued to a single practice of medicine, podiatry or dentistry to own and operate a clinical laboratory at stated locations exclusively for the patients or the members of that practice, and is limited to simple tests and those tests or categories of tests set forth by the regulations promulgated pursuant to this Act; or a permit issued to a local health authority or designated agency to own and operate a clinical laboratory at stated locations without acceptance of referred testing, and is limited to those tests or categories of tests set forth by regulations promulgated pursuant to this Act.* (Section 2-108 of the Act)~~

~~*"Class II Permit" means a permit issued to the owner of a clinical laboratory at a stated location in which the laboratory is operated and maintained exclusively for the patients of the physicians, podiatrists or dentists who practice at that location and who own the laboratory or are employed by the owner; or*~~

> ~~*A permit issued to a local health authority or designated agency to own and operate a clinical laboratory at stated locations and at which referred testing may be accepted from other local health authorities or designated agencies; or*~~
>
> ~~*A clinical laboratory which fits the definition of a Class I Permit Laboratory but performs more complex tests than those under a Class I Permit.*~~

~~*Tests performed by a laboratory holding a Class II Permit shall be limited to*~~

~~*those tests or categories of tests set forth in the regulations promulgated pursuant to this Act.* (Section 2-109 of the Act)~~

~~*"Class III Permit" means a permit issued to the owner of a clinical laboratory which is operated and maintained exclusively for the purpose of conducting health screening tests by a person, corporation, organization, association or group which provides health screening services in accordance with provisions of Section 2-120 either directly or indirectly on a for-profit basis.* (Section 2-100 of the Act)~~

"CLIA Law" – the Clinical Laboratory Improvement Amendments of 1988 (amendments to the Public Health Service Act (42 USC 263a)) and the related federal regulations. Establishes quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid, and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or of assessment of health.

"Clinical Laboratory" or "Laboratory" – ~~*means*~~ *a facility which performs laboratory tests or issues reports resulting from* ~~*such*~~ *tests.* For the purposes of this Part, "Clinical Laboratory" or "Laboratory" does not include forensic laboratories. (Section 2-103 of the Act)

~~*"Complex Test" means any test which does not meet the definition of a simple test.* (Section 2-119 of the Act).~~

"Controlled Substance" – ~~means~~ a drug, substance, or immediate precursor as defined in the Illinois Controlled Substances Act.~~Illinois Controlled Substance Act (Ill. Rev. Stat. 1987, ch. 56½, pars. 1100 et seq., as now and hereafter amended.)~~

~~"Dental Practice Act" means The Illinois Dental Practice Act (Ill. Rev. Stat. 1987, ch. 111, par. 2301 et seq., as now and hereafter amended.)~~

"Demonstration of Proficiency~~proficiency~~" – ~~means the~~ when a laboratory meets the standards for acceptable proficiency testing as stated in Section 450.720(a)~~(f)~~ by means of on site analysis of specimens sent to the laboratory by agencies approved by the Department for that purpose.

"Department" – ~~means~~ *the Department of Public Health of the State of Illinois*. (Section 2-105 of the Act)~~the Illinois Department of Public Health.~~

~~*"Designated Agency" means an association, organization, group or agency which operates a clinical laboratory for the purpose of meeting the requirements of a state or federal program.* (Section 2-122 of the Act).~~

"Director" – the Director of the Department of Public Health.

"Director of Clinical Laboratory" or "Laboratory Director" – *an individual who administers the technical and scientific operation of a clinical laboratory, including the reporting of the findings of clinical laboratory tests.* (Section 2-104 of the Act)

"FDA" − Food and Drug Administration within the United States Department of Health and Human Services (HHS).

"Full-time Experience~~experience~~" – ~~means~~ experience in the field being referred to consisting of at least 35 hours per week conducting activities required by the specific position or field such as conducting the tests referred to in Section 2-103 of the Act.

"Health Screening" – tests or categories of tests set forth in the Act and this Part *that are performed for the purpose of assessing a phase of the general state of health of human subjects* (Section 2-120 of the Act).

"HHS" – the United States Department of Health and Human Services.

~~"Hospital Licensing Act" means the Hospital Licensing Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 142 et seq., as now and hereafter amended.)~~

~~*"License" means a license issued to the owner, local health authority or designated agency or person to operate a clinical laboratory at a stated location to accept specimens from any person authorized to submit such specimens under this Act, with test limitations based upon the qualifications of the Director as set forth by the regulations promulgated pursuant to this Act.* (Section 2-111 of the Act).~~

"Licensed Clinical Laboratory" – laboratory licensed (certified) by the Centers for Medicare & Medicaid Services (CMMS) in accordance with CLIA.

~~*"Local Health Authority" means the full-time, official health department or Board of Health, as recognized by the Department, which has jurisdiction over a particular geographical area.* (Section 2-121 of the Act).~~

~~"Medical Practice Act" means the "Medical Practice Act of 1987" (Ill. Rev. Stat. 1987, ch. 111, pars. 4401-1 et seq., as now and hereafter amended.)~~

~~"Minor Test" means any uncomplicated laboratory examinations and procedures~~

~~which the Director of the Department determines have an insignificant risk of erroneous result including those which have been approved by the United States Food and Drug Administration for home use, which employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible. Tests determined by the Director to be "minor" and permissible for a Registration class laboratory are set forth in Section 450.35(a).~~

"Physician" – ~~*means,*~~ *unless otherwise indicated in the~~this~~ Act* and this Part*, a person licensed by the Department of Professional Regulation, pursuant to the requirements of the Medical Practice Act of 1987;* (i.e., a physician licensed to practice medicine in all its branches and a chiropractic physician) *or a person licensed as a physician under the laws of another state or territory of the United States.* (Section 2-116 of the Act).

~~"Podiatry Act" means Podiatric Medical Practice Act of 1987 (Ill. Rev. Stat. 1987, ch. 111, pars. 4801 et seq., as now and hereafter amended.)~~

"Prepackaged Reagent Analyzer~~Analyser~~" – ~~means~~ an automated instrument in which a specimen or a diluted specimen is reacted with reagents contained within individual packet(s) containing all of the measured reagents required for the analysis for a given analyte.

~~*"Proficiency Testing" means a program for monitoring laboratory performance on a periodic basis which is adopted or approved by the Department.* (Section 1-123 of the Act.)~~

~~*"Simple Test" means a test or categories of tests which generally have the following characteristics:*~~

~~*Interpretation of a visual signal by pattern recognition, color definition or numeric information using an established control example* which can be observed directly by the operator and requires no manipulation or interpolation by the operator to derive a result; *or*~~

~~*The use of simple addition, subtraction, multiplication or division; or*~~

~~*The use of manufacturer-prepared reagents or solutions which are combined without requiring numerous* (i.e. no more than five sequential steps which should not include sample acquisition or sample preparation such as centrifuge to obtain serum) *specific calibrated volume measurements or sequential applications.*~~

~~In addition, the following considerations are used to determine if a test or test~~

~~procedure meets the definition of Simple Test: the examinations and procedures performed and the methodologies employed, the degree of independent judgment involved, the amount of interpretation involved, the difficulty of the calculations involved, the calibration and quality control requirements of the instruments used, the type of training required to operate the instruments used in the methodology, and such other factors as the Director considers relevant.~~

~~*Interpretation of the types of tests or categories of test which meet this definition shall be determined by the Department in consultation with the* Clinical Laboratory and Blood Bank *Advisory Board* established by Section 5-101 of the Act. (Section 2-118 of the Act).~~

~~The Department will compile a list of tests and test procedures which it determines meets the definition of a simple test. Such compilation will be available upon request and updated annually.~~

"Single Practice~~practice~~" – ~~means~~ a medical, dental or podiatric practice, or a partnership, professional service corporation, or medical corporation of one or more licensed practitioners who share facilities, personnel, income and expenses for a clinical laboratory that is used solely as an adjunct to the care of patients of the members of the single practice.

"Test" – ~~means~~ laboratory examinations and issuance of reports resulting from the biological, microbiological, serological, chemical, immunohematological, radioimmunological, hematological, biophysical, cytological, pathological, toxicological or other examination of materials derived from the human body for the purposes of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of humans including determining drug use by humans. (Section 2-117 of the Act).

"Toxicology Laboratory" – ~~means~~ a licensed laboratory that~~which~~ performs tests to detect drug abuse in the workplace, among job applicants, or for other similar purposes.

"Waived Test" – a test system, assay or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under Section 353(d)(3) of the Public Health Service Act that has been determined to be so simple as to pose no risk of harm if performed incorrectly.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.20 ~~Permit and~~ License (Certification) Application

~~a)~~ ~~*A laboratory that is required to obtain a license or permit pursuant to this Act by July 1, 1989, but was previously exempt from such requirement, shall submit an application to the Department, but will have until December 31, 1989, to comply with this requirement. Any such laboratory which complies with this deadline will be permitted to continue operation until receipt of a permit or license or notice of denial of application for a permit or license from the Department.*~~ ~~(Section 3-103(b) of the Act)~~

a~~b~~) All applications shall be submitted on forms provided by the Department, shall be notarized, and shall include all information requested on the form.

b~~c~~) If ~~during the calendar year in which~~ the licensed (certified) provider~~license, permit, or renewal thereto~~ has ~~been issued there is~~ a change of owner, location, or name of the laboratory, the Department shall be notified of the change in writing within 30 days following the change by one of the following methods:~~prior to such change.~~

1) U.S. Mail to: Illinois Department of Public Health, Office of Health Care Regulation, Division of Health Care Facilities and Programs, 525 West Jefferson Street, Fourth Floor, Springfield, Illinois 62761; or

2) Facsimile to: 217-782-0382, attention: Division of Health Care Facilities and Programs.

~~d)~~ ~~If the license or permit is to be issued to two or more persons who are co/owners, all such persons shall be identified upon the application for license or permit or renewal of license or permit and all such persons shall sign such application and it shall be notarized.~~

~~e)~~ ~~An application for a license or permit, where the owner is a corporation, shall clearly disclose the names of all persons owning 5% or more of the shares of the corporation. A duly authorized officer of the corporation shall sign the application and it shall be notarized.~~

c~~f~~) The description of the program shall be provided in sufficient detail to permit the Department to determine the fields of science represented by the services of the laboratory and the tests which may fall within the scope of its program and services.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.30 Laboratories Covered

The following are required to be licensed (certified) pursuant to CLIA Law:

a) All clinical laboratories and blood banks located within the State of Illinois. This includes facilities that issue reports resulting from laboratory examinations, but do not perform laboratory examinations at that facility. (See Section 2-103 of the Act.)

b) Laboratories located in hospitals licensed under the Hospital Licensing Act that are not operated by the governing authority of the hospital, including laboratories operating under a lease arrangement with another person or entity.

c) Laboratories outside of Illinois receiving specimens referred from laboratories located in Illinois shall be certified under CLIA Law, or certified by, and in good standing with, their state laboratory program.

~~a) This Section provides references to help understand the differences among these laboratories. The Department assigns an identification number to a laboratory at the time of license or permit application. This number is only for purposes of filing material for that laboratory in the Department. Such identification number is not a license or permit. A license or permit is issued only after an inspection of the facility finds compliance with all pertinent requirements, except for a class I permit laboratory where an inspection is not required.~~

~~1) An exempt laboratory meets the criteria set forth in Section 1-103(c) of the Act, and Sections 450.30(c)(3) and 450.35(a) of this Part.~~

~~2) A class I permit laboratory meets the criteria set forth in Section 2-108 of the Act; Section 6-101(2)(a) of the Act; and Sections 450.30(b) and 450.35(b) of this Part.~~

~~3) A class II permit laboratory meets the criteria set forth in Section 2-109 of the Act; Section 6-101(2)(b) of the Act; and Sections 450.30(b) and 450.35(c) of this Part.~~

~~4) A class III permit laboratory meets the criteria set forth in Section 2-110 of the Act; Section 6-101(2)(c) of the Act; and Sections 450.30(b) and 450.35(d) of this Part.~~

~~5) A licensed laboratory meets the criteria set forth in Section 2-111 of the Act; Section 6-101(2)(d) of the Act; and Sections 450.30(b) of this Part with no testing limitations, provided the director qualifies.~~

~~b) The following are required to obtain a permit or be licensed pursuant to the Act:~~

1) All clinical laboratories and Blood Banks located within the State of Illinois except as otherwise provided in Section 450.30(c). This includes facilities that issue reports resulting from laboratory examinations, but do not perform laboratory examinations at that facility. (See Section 2-103 of the Act).

2) Laboratories located in hospitals licensed under the Hospital Licensing Act but where the laboratory is not operated by the governing authority of such hospital, including laboratories operating under a lease arrangement with another person or entity.

3) Laboratories outside of Illinois receiving specimens referred from laboratories located in Illinois that are required to obtain a license or permit under this Act.

c) The following are not required to obtain a permit or be licensed under the Clinical Laboratory Act:

1) Clinical laboratories operated by the United States Government.

2) Clinical laboratories located in hospitals licensed under the Hospital Licensing Act that are under the control of the governing board of such hospitals owned by the exact same entity identified as owner/operator of the hospital as indicated on the last hospital license application filed with the Department; located at the same site and contiguous with the hospital; subject to the regulations and hospital by-laws; and where the entity which receives payment for the laboratory services is the same entity that owns the hospital.

3) Exempt Laboratories: *Laboratories which fit the definition of Class I Permit Laboratories but perform a small number of minor tests as compared to other Class I Permit Laboratories as set forth by regulations promulgated pursuant to this Act* (See Section 450.35(a)), *or any tests performed by the physician, podiatrist or dentist for the benefit of his or her patients, do not require a license or permit.* (See Section 1-103(c) of the Act).

4) *Laboratories which only perform health screenings in accordance with Section 2-120 of The Act* and Sections 450.1300, 450.1310, 450.1320, and 450.1330 of this Part, *on a not-for-profit or free-of-charge basis are exempt from all other provisions of this Act.* (Section 1-103(d) of the Act)

~~5)~~ ~~*Law enforcement agencies and probation and court services departments performing urinalysis and blood tests to determine drug and alcohol use by humans.* (Section 1-103(e) of the Act)~~

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.35 Testing Limitations for Exempt, Permit and Licensed Laboratories (Repealed)

~~This Section explains the tests as defined in Section 2-117 of the Act which can be performed by each of the laboratories regulated by the Act.~~

~~a)~~ ~~Exempt Laboratories as defined in Section 1-103(c) of the Act may perform the following tests:~~

~~1)~~ ~~Specific tests and test procedures permissible are the following:~~

~~A)~~ ~~Urinalysis measured by the use of a chemically impregnated strip (dipstick) or tablet;~~

~~B)~~ ~~Hematocrit by centrifugation;~~

~~C)~~ ~~Occult blood;~~

~~D)~~ ~~Urine pregnancy testing (semi-quantitative chorionic gonadotropin);~~

~~E)~~ ~~Hemoglobin;~~

~~F)~~ ~~Red Blood Cell (RBC) sickle cell screen using dithionite, sodium hydrosulfite;~~

~~G)~~ ~~Wet mounts for Yeast or Trichomonas;~~

~~H)~~ ~~Blood cholesterol;~~

~~I)~~ ~~Blood glucose;~~

~~J)~~ ~~Erythrocyte protoporphyrin using a hematofluorometer;~~

~~K)~~ ~~Screening for drugs of abuse by latex agglutination or any other method which meets the simple test definition;~~

~~L) Gonorrhea limited to cultures for growth or no growth, oxidase and lactidase, Gram stain;~~

~~M) Microscopic examination of pinworm preparation; and~~

~~N) *Strep Screening Tests:* Rapid group A strep antigen tests. (Section 1-103(c) of the Act)~~

~~2) *Any test performed* (i.e., conducted and interpreted) *by a physician, podiatrist or dentist for the benefit of his or her patients. (Section 1-103(c) of the Act);~~

~~3) Any tests and test procedures approved by the United States Food and Drug Administration for over the counter sale.~~

~~4) RPR tests for syphilis may be performed by exempt laboratories operated by local health departments under the following conditions:~~

~~A) The Department has determined that the area served by the laboratory has a high incidence of early syphilis;~~

~~B) The laboratory has a written procedure for the performance of RPR syphilis testing which complies with Section 450.1140 and Section 450.1150(f)(l) of this Part and maintains documentation of compliance with this procedure;~~

~~C) The laboratory has written procedures for training of personnel who perform the tests;~~

~~D) The laboratory successfully participates in an approved proficiency testing program for syphilis serology;~~

~~E) All specimens tested are submitted to a laboratory operated by the Department for confirmation of the test results; and~~

~~F) The laboratory is subject to inspection by the Department and agrees to immediately cease RPR syphilis testing if the Department determines that the laboratory is not in compliance with these conditions.~~

~~b) Class I Permit Laboratories as defined in Section 2-108 of the Act may perform the following tests:~~

~~1) All tests that can be performed by Exempt Laboratories;~~

~~2) Any *simple tests* as defined in Section 450.10 (Section 2-108 of the Act); and~~

~~3) *Those tests or categories of tests set forth by the regulations promulgated pursuant to the Act.* The Department may give approval to a Class I permit laboratory to perform up to three tests which do not fall within the definition of a simple test, when the laboratory director submits documentation describing the purpose of each test, how it is performed, the specific training and experience of the personnel performing the test(s) and necessary quality control procedures appropriate to the test(s), and the extent of supervision provided by the laboratory director. The Department shall grant approval based upon the following criteria:~~

~~A) the test(s) is unique to a specific healthcare practice and not readily available from a licensed clinical laboratory (e.g., not performed by a licensed clinical laboratory or hospital laboratory within 50 miles); or~~

~~B) on-site prompt results (e.g., results are required in less time than sending a specimen to a reference laboratory) are necessary for the treatment or care of the patients of the healthcare provider because of the nature of the practice.~~

~~c) Class II permit Laboratories as defined in Section 2-109 of the Act may perform the following tests:~~

~~1) All tests that can be performed by Exempt Laboratories;~~

~~2) All tests that can be performed by the Class I laboratory as detailed in subsection (b).~~

~~3) Any complex tests.~~

~~d) Class III Permit Laboratories as defined in Section 2-110 of the Act may perform the following tests:~~

~~Any health screening tests as defined in Section 450.1300(a).~~

~~e) Licensed Clinical Laboratories as defined in Section 2-111 of the Act may perform the following tests:~~

~~1) All tests that can be performed by Exempt Laboratories;~~

~~2)~~ ~~All tests that can be performed by the Class I laboratory as detailed in subsection (b).~~

~~3)~~ ~~Any complex tests.~~

(Source: Repealed at 44 Ill. Reg. _____, effective _____)

Section 450.50 Incorporated and Referenced Materials

The following materials are incorporated or referenced in this Part:

a) The following State of Illinois Statutes are referenced in this Part:

1) Illinois Clinical Laboratory and Blood Bank Act [210 ILCS 25]~~Illinois Clinical Laboratory Act (Ill. Rev. Stat. 1987, par. 621 et seq. as amended by P.A. 85-1025, effective June 30, 1988; 85-1202, effective August 25, 1988; P.A. 85-1251, effective August 30, 1988.) (Section 450.10)~~

~~2)~~ ~~Illinois Blood Bank Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 601-101 et seq.) (Section 450.10 and 450.1200(a)(1))~~

2~~3~~) Illinois Dental Practice Act [225 ILCS 25]~~(Ill. Rev. Stat. 1987, ch. 111, par. 2301 et seq.) (Section 450.10)~~

3~~4~~) Hospital Licensing Act [210 ILCS 85]~~(Ill. Rev. Stat. 1987, ch. 111½, pars. 142 et seq.) (Section 450.10, 450.30, 450.1200(a)(1), 450.1300(b)(3))~~

4~~5~~) Medical Practice Act of 1987 [225 ILCS 60]~~(Ill. Rev. Stat. 1987, ch. 111, pars. 4401 et seq.) (Section 450.10)~~

5~~6~~) Podiatric Medical Practice Act of 1987 [225 ILCS 100]~~(Ill. Rev. Stat. 1987, ch. 111, pars. 4801 et seq.) (Section 450.10)~~

6~~7~~) Code of Civil Procedure, Article III (Administrative Review Law) [735 ILCS 5/Art. III]~~Administrative Review Law (Ill. Rev. Stat. 1987, ch. 110, pars. 3-101 et seq.) (Section 450.40(b)(5))~~

7~~8~~) Illinois Controlled Substances Act [720 ILCS 570]~~(Ill. Rev. Stat. 1987, ch. 56½, pars. 1100 et seq.) (Section 450.10)~~

b) The following State of Illinois Regulations are referenced in this Part:

1) Sewer Discharge Criteria (35 Ill. Adm. Code 307)
~~(Section 450.330(d)(5))~~

2) Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities (35 Ill. Adm. Code 724)
~~(Section 450.330(e)(4)(A))~~

3) Solid Waste Disposal: General Provisions (35 Ill. Adm. Code 809)
~~(Section 450.330(e)(4)(c)(i))~~

c) The following federal guidelines~~Federal Guidelines~~, statutes~~Statutes~~, federal regulations~~Federal Regulations~~, and other materials are incorporated by reference:

1) Federal Regulations and Statutes:

A~~1~~) 42 CFR 493, Laboratory Requirements (CLIA regulations) (October 1, 2018)~~42 CFR 405, Subpart M (1988)~~
~~(Section 450.10)~~

B~~2~~) 21 CFR 600-680, Biologics (April 1, 2018~~(1988~~)
~~(Section 450.1150(g)(1))~~

C) Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, Title II – Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform, Section 264 – Recommendations with Respect to Privacy of Certain Health Information (August 21, 1996), Assistant Secretary for Planning and Evaluation, Room 415F, U.S. Department of Health and Human Services, 200 Independence Avenue, SW, Washington DC 20201
Also available online at: https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996

D) 42 USC 263a, Certification of Laboratories (January 12, 2018)

~~3)~~ ~~Laboratory Qualification Appraisal Personnel Form Health Care Financing Authority (HCFA) HCFA-3084-OMB No. 0938-0049 (See Section 400.210(a), 450.410(b), 450.420(a), 450.430(a), 450.440(a) and 450.450(a))~~

2) Federal Guidelines and Other Materials:

A~~4~~) GP17-A3 Clinical Laboratory Safety; Approved Guideline – Third

Edition, Clinical and Laboratory Standards Institute (CLSI) (June 2012)~~National Committee for Clinical Laboratory Standards (NCCLS)~~, 950 West Valley Road, Suite 2500, Wayne PA 10987
Also available online at: https://clsi.org/media/1381/gp17a3_sample.pdf ~~"Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluid and Tissue" Document #M29-T, Vol. 9, #1 (January 1989), 771 East Lancaster Avenue, Villanova, PA 19085~~

~~5)~~ ~~42 CFR 405.1317 (b)(1) (1988)~~

B) Public Health Service Act, Subpart 2, Section 353 – Clinical Laboratories, Certification of Laboratories (1997), Public Health Law, CDC, 1600 Clifton Road, Atlanta GA 30329-4027 ~~(Section 450.10)~~
Also available online at: https://wwwn.cdc.gov/cliac/pdf/Addenda/cliac0910/Addendum%20C_Yost.pdf

C~~6~~) Reference Volume for Human Cytogeneticists, Molecular Geneticists, Technicians, and Students for the Interpretation and Communication of Human Cytogenetic and Molecular Cytogenomic Nomenclature: ISCN 2016 − An International System for Human~~of~~ Cytogenetic Nomenclature (2016), S. Karger AG, Medical and Scientific Publishers, P.O. Box CH~~Ch~~-4009 Basel, ~~(~~Switzerland~~) 1985. (See Section 450.1150(j)(3)(C)(i))~~

d) All incorporations by reference of federal regulations and the standards of nationally recognized organizations refer to the regulation and standards on the date specified and do not include any additions or deletions subsequent to the date specified.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

SUBPART B: DIRECTORS OF CLINICAL LABORATORIES

Section 450.210 Qualifications of the Director of a Clinical Laboratory

A director candidate shall meet one or more options of the qualification requirements in 42 CFR 493, Subpart M.

~~a)~~ ~~*Qualifications of Directors. Every clinical laboratory shall be under the supervision and direction of a Director who possesses one of the following qualifications.* These qualifications must be documented on the Department form~~

~~entitled "Laboratory Personnel Qualifications Appraisal". (See Section 450.50(c)(3))~~

~~1)~~ ~~*The individual is a physician licensed to practice medicine in all its branches in Illinois and certified by the American Board of Pathology or the American Osteopathic Board of Pathology in clinical pathology, or who possesses qualifications which are equivalent to such certification (Board eligible).*~~

~~2)~~ ~~*The individual is a physician licensed to practice medicine in all its branches in Illinois with special qualifications in the performance of the test or tests offered by the clinical laboratory, whose training and experience are acceptable to the Department.*~~

~~A)~~ ~~A physician having not less than one year of post-graduate training in diagnostic laboratory procedures in a residency training program approved for training purposes by the American Board of Pathology or the American Osteopathic Board of Pathology.~~

~~B)~~ ~~A physician having not less than two years of supervised experience in an approved clinical laboratory carrying out procedures in the field or fields or science which encompass the program and services provided by the laboratory which this individual will direct.~~

~~C)~~ ~~To be director of a genetics laboratory, the physician shall have 4 or more years of post-graduate genetics laboratory experience in an approved clinical laboratory.~~

~~D)~~ ~~To be director of a histocompatibility laboratory, the physician shall have 4 or more years of immunology laboratory experience in an approved clinical laboratory, subsequent to becoming a physician, 2 years of which have been in histocompatiblity testing.~~

~~E)~~ ~~To be director of a toxicology laboratory which performs tests for controlled substances, the physician shall have 4 or more years of post-graduate experience in an approved clinical laboratory which performs tests for controlled substances or have formal academic education from an accredited institution in drug metabolism, drug kinetics, and the use and limitations of analytical procedures used in drug analysis.~~

~~3)~~ ~~*In the case of a laboratory, the principal place of business of which is*~~

~~*outside the State of Illinois, the individual is a physician licensed to practice medicine in all of its branches in that state and possesses special qualifications in the performance of the test or tests offered by the clinical laboratory with training and experience acceptable to the Department.*~~

~~A)~~ ~~A physician having not less than one year of post-graduate training in diagnostic laboratory procedures in a residency training program approved for training purposes by the American Board of Pathology or the American Osteopathic Board of Pathology.~~

~~B)~~ ~~A physician having not less than two years supervised experience in an approved clinical laboratory carrying out procedures in the field or fields of science which encompass the program and services provided by the laboratory which this individual will direct.~~

~~C)~~ ~~To be director of a genetics laboratory, the physician shall have 4 or more years of post-graduate genetics laboratory experience in an approved clinical laboratory.~~

~~D)~~ ~~To be director of a histocompatibility laboratory, the physician shall have 4 or more years of immunology laboratory experience in an approved clinical laboratory, subsequent to becoming a physician, 2 years of which have been in histocompatibility testing.~~

~~E)~~ ~~To be director of a toxicology laboratory which performs tests for controlled substances, the physician shall have 4 or more years of post-graduate experience in an approved clinical laboratory which performs tests for controlled substances or have formal academic education from an accredited institution in drug metabolism, drug kinetics, and the use and limitations of analytical procedures used in drug analysis.~~

~~4)~~ ~~*The individual is a physician* (i.e. physician licensed to practice medicine in all its branches or a chiropractic physician)~~, ~~*dentist or podiatrist licensed in Illinois.*~~

~~5)~~ ~~*The individual holds a degree above baccalaureate level from a college or university acceptable to the Department, with a major in chemical or biological sciences and has satisfied the Department of his training and proficiency in those tests for which this license is sought.*~~

~~A)~~ ~~An individual who holds an earned graduate degree above the~~

~~baccalaureate level from an accredited institution in a medical laboratory science or with a chemical or biological science as a major subject may direct a laboratory which requires a class I, II, or III permit or a license, provided the individual documents that the individual has had 3 more years of full-time clinical laboratory training and experience in an approved clinical laboratory, subsequent to graduation, in each area of the laboratory in which testing is performed. The laboratory areas are bacteriology/mycology, parasitology, virology, immunology/serology, hematology, immunohematology, and chemistry. Experience as a technologist in an approved clinical laboratory which was gained prior to acquiring the graduate degree may be substituted on an equivalency basis of 1.5 years of such experience for every 1 year of post degree training and experience required; and experience as a general supervisor in an approved clinical laboratory, which was gained prior to acquiring such degree, may be substituted on a 1-for-1 basis. Such documentation shall be made on a form entitled "Laboratory Personnel Qualifications Appraisal" (See Section 450.50(c)(3)).~~

~~B)~~ ~~To be director of a histocompatibility laboratory, the individual shall hold an earned doctoral degree from an accredited institution with a chemical or biological science as a major subject and have 4 or more years of postdoctoral laboratory experience in immunology in an approved clinical laboratory, 2 of which have been in histocompatibility testing.~~

~~C)~~ ~~To be director of a genetics laboratory, the individual shall hold an earned doctoral degree from an accredited institution with a chemical or biological science as a major subject and have 4 or more years of postdoctoral genetics laboratory experience in an approved clinical laboratory.~~

~~D)~~ ~~To be director of a toxicology laboratory which performs tests for controlled substances, the individual shall hold an earned doctoral degree from an accredited institution with a chemical or biological science as a major subject and have 4 or more years of post-graduate experience in an approved clinical laboratory which performs tests for controlled substances; or have formal academic education from an accredited institution in drug metabolism, drug kinetics, and the use and limitations of analytical procedures used in drug analysis.~~

~~6)~~ ~~*An individual listed as the Director, prior to August 23, 1965, of one clinical laboratory which was registered with the Department under the provisions of this Act, may continue to direct one laboratory, and an individual who directed two such laboratories simultaneously may continue to direct two laboratories, except that the Department, upon recommendation of the Clinical Laboratory and Blood Bank Advisory Board , may, as a condition precedent to the issuance of an original license hereunder, require such individual to pass a practical examination in the event that it deems such an examination necessary to determine the competence of the individual to direct a clinical laboratory.*~~ ~~The Department will not require a practical examination.~~

~~7)~~ ~~*The individual is a physician licensed to practice medicine in all its branches in Illinois.*~~

~~8)~~ ~~To be director of a pathologic anatomy laboratory, the individual *must be a physician licensed to practice medicine in all its branches in Illinois and certified or determined to be board eligible by the American Board of Pathology in anatomic pathology or the American Osteopathic Board of Pathology in anatomic pathology, or the individual is a dentist licensed in Illinois and certified by the American Board of Oral Pathology; except that bone marrow interpretations may be done by a hematologist who is certified or determined to be Board eligible by the American Board of Internal Medicine.*~~

~~b)~~ ~~*Minimum requirements for laboratory direction and staffing. A permit or license to operate a clinical laboratory shall be issued only if the following technical staff are employed to provide supervision and direction during testing as required by regulations promulgated pursuant to this Act:*~~

~~1)~~ ~~*A class I permit requires a Director qualified under subsections (1), (2), (4), (5), (6) or (8) of subsection (a) of this Section to provide supervision and direction, with or without a laboratory assistant.*~~

~~2)~~ ~~*A class II permit requires a Director qualified under subsections (1), (2), (5), (6), (7) or (8) of subsection (a) of this Section to provide supervision and direction, with the employment of technicians or technologists.*~~

~~3)~~ ~~*A class III permit requires a Director qualified under subsections (1), (2), (5), (6) or (7) of subsection (a) of this Section to provide supervision and Direction, with the employment of laboratory assistants or technicians.*~~

~~4)~~ ~~*A license requires a Director qualified under subsections (1), (2), (3), (5),*~~

~~*(6) or (8) of subsection (a) of this Section to provide supervision and direction, with the employment of a general supervisor if necessary to provide supervision in the absence of the Director.*~~

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.220 Operational Participation of the Director

a) The laboratory director is responsible for the operation and administration of the laboratory, including the employment of personnel who are qualified and competent to perform test procedures, maintain records, and report test results promptly, accurately and proficiently to assure compliance with applicable CLIA Law.

b) The laboratory director, if qualified, may perform the duties of the technical supervisor, technical or clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications.

c) The laboratory director shall be accessible to the laboratory to provide onsite, telephone or electronic consultation.

d~~a~~) The laboratory director shall~~must~~ follow the weekly schedule established in accordance with Section 450.1110(d), except for absences due to emergencies, illness, or professional meetings. In case of an absence for vacation or other purposes that~~which~~ does not exceed 30 days, the owner shall ensure director coverage by designating an acting director who is qualified to direct that laboratory.

e~~b~~) If the laboratory director is absent for~~In case of an absence which is~~ more than 30 days, the owner shall designate an acting laboratory director~~ to direct the laboratory in the Director's absence~~ who meets the qualifications in 42 CFR 493, Subpart M~~set forth in Section 6-101 of the Act which are appropriate for the permit or license held by the laboratory~~. If the absence of the laboratory director will be permanent, the owner shall immediately submit a request for a laboratory director change to the Department.~~The owner shall submit to the Department immediately after 30 days has elapsed, a personnel form for the acting director. This individual may be the same individual designated in accordance with Section 450.220(a) or another individual. The acting director may continue to function as director for a period of 90 days after the personnel form is received.~~

~~c) An acting director may not serve as director for a period of time exceeding 120 days, 90 days after the personnel form was received by the Department, unless the~~

~~owner informs the Department that the acting director is now the director.~~

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.230 Number of Laboratories Permitted to Operate

a) The director of a clinical laboratory shall not direct more than five moderate or high complexity~~three~~ clinical laboratories, as defined in 42 CFR 493~~or blood banks~~. This limitation does not preclude a laboratory director from serving additional laboratories as a technical supervisor, technical or clinical consultant, general supervisor, or testing personnel~~consultant, general supervisor, or acting director~~.

b) The director of a clinical laboratory shall~~must~~ actively participate in the activities and programs of the clinical laboratory~~; therefore, attendance of brief duration sufficing only for signature of reports or other nominal administrative duties will not constitute compliance with Section 6-104 of the Act~~.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

SUBPART D: QUALIFICATIONS OF PERSONNEL

Section 450.410 General Supervisor

In a licensed (certified) laboratory, the general supervisor shall be accessible to the laboratory to provide on-site, telephone, or electronic consultation, and shall meet qualification requirements in 42 CFR 493, Subpart M.

~~a)~~ ~~Duties~~

~~In a licensed laboratory, there shall be at least one qualified director or supervisor on the laboratory premises during all hours in which tests are performed. In the absence of the director, the supervisor shall supervise technical personnel and reporting of findings, perform tests requiring special scientific skills and be held responsible for the proper performance of all laboratory procedures. During periods of time when the laboratory is open for emergency testing only, a director or supervisor is not required to be on the premises provided a qualified technologist (See Section 450.420) performs the emergency tests and the director or supervisor who is responsible for the work reviews and documents the review of the results during the next duty period when the laboratory is open to provide other than emergency testing or within 24 hours, whichever occurs first. An emergency shall be determined by the physician attending the patient, and in order to clearly indicate an emergency exists, the laboratory request form shall include an appropriate designation such as "Stat".~~

b) An individual who meets one of the following qualifications shall qualify as general supervisor. These qualifications must be documented on the Department's form entitled "Laboratory Personnel Qualifications Appraisal". (See Section 450.50(c)(3)):

1) The individual is a physician licensed to practice medicine in all of its branches or has an earned doctoral degree from an accredited institution in a medical laboratory science such as microbiology and clinical chemistry and subsequent to graduation has had at least 1 year of full-time experience in one of the laboratory specialties in an approved clinical laboratory.

2) The individual has a Master of Arts or Master of Science degree from an accredited institution in a medical laboratory science such as microbiology and clinical chemistry and subsequent to graduation has had at least 1 year of full-time laboratory experience in an approved clinical laboratory.

3) The individual is qualified as a medical technologist pursuant to the provisions of Section 450.420. If the individual qualifies as a medical technologist because the individual has successfully passed the United States Public Health Service Exam prior to July 1, 1989, the individual has either:

A) an associate degree or at least 60 semester hours of academic credit from an accredited institution, including at least 12 semester hours in chemistry and biology courses and four years of full-time laboratory experience in an approved clinical laboratory; or

B) six years of experience as a medical technologist in an approved laboratory.

4) With respect to the specialty of diagnostic cytology, qualifies as a supervisory cytotechnologist because the individual qualifies as a cytotechnologist under Section 450.430(a), (b) or (c) and has had at least 4 years of full-time experience within the preceding 10 years as a cytotechnologist in a laboratory directed by an individual qualified to direct such a laboratory under Section 6-103 of the Act within the preceding 10 years.

5) With respect to the specialty of genetics, qualifies as a supervisor because the individual meets the requirements of subsections (b)(1), (2) or (3) above a minimum of two years of experience, except that the experience

~~requirements must be in a genetics laboratory.~~

~~c)~~ ~~Exception to subsections (b) (1), (2), and (3) above~~
~~An individual serving as general supervisor of a clinical laboratory on September 15, 1970 and having had at least 15 years of pertinent laboratory experience prior to September 15, 1970 may continue to serve as supervisor of said laboratory: provided, that a minimum of 30 semester hours credit toward a Bachelor's degree with a chemical, physical or biological science as his major subject shall reduce the required years of experience by 2 years, with any additional hours further reducing the required years of experience at the rate of 15 hours for 1 year.~~

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.420 **Testing Personnel**~~**Medical Technologist**~~

A testing personnel candidate shall meet one or more options of the qualification requirements in 42 CFR 493, Subpart M.

~~a)~~ ~~An individual who meets one of the following qualifications shall qualify as a technologist. These qualifications must be documented on the Department's form entitled "Laboratory Personnel Qualifications Appraisal". (See Section 450.50(c)(3))~~

~~1)~~ ~~The individual has an earned Bachelor's degree in medical technology from an accredited college or university.~~

~~2)~~ ~~The individual has 3 academic years of study (a minimum of 90 semester hours or equivalent) in an accredited college or university which meets the specific requirement for entrance into, and the successful completion of a course of training of at least 12 months in, a school of medical technology accredited by one of the agencies recognized by the U.S. Office of Education for the accreditation of training programs for medical technologists, as distinguished from training programs for medical laboratory technicians.~~

~~3)~~ ~~The individual has an earned Bachelor's degree from an accredited college or university course of studies which meets all academic requirements for a in one of the chemical, physical, or biological sciences and in addition at least 1 year of clinical laboratory experience and/or training in an approved clinical laboratory in the laboratory field or fields in which the individual performs tests.~~

~~4)~~ ~~The individual has completed 3 years (90 Semester hours or equivalent in~~

~~quarter hours) in an accredited college or university with a distribution of courses as shown below, and, in addition, successful experience and/or training covering several fields of medical laboratory work of such length (not less than 1 year), and of such quality that this experience or training in an approved clinical laboratory in the laboratory field or fields in which the individual performs tests. The specified courses must have included lecture and laboratory work. Survey courses are not acceptable.~~

~~A)~~ ~~For those whose training was completed prior to September 15, 1963: academic training must include at least 24 semester hours in chemistry and biology courses of which not less than 9 semester hours must have been in chemistry and must have included at least 6 semester hours in inorganic chemistry, and not less than 12 semester hours must have been in biology courses pertinent to the medical sciences.~~

~~B)~~ ~~For those whose training was completed after September 15, 1963: academic training must include 16 semester hours in chemistry courses which must have included at least 6 semester hours in general chemistry and the remaining semester hours in analytical chemistry, organic chemistry or physical chemistry and which are acceptable toward a major in chemistry; 16 semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in biological sciences; and 3 semester hours of mathematics.~~

~~b)~~ ~~Exceptions to subsection (a) above~~

~~1)~~ ~~An exception to subsection (a) may be made if~~

~~A)~~ ~~The technologist was performing the duties of a medical technologist on, or within the 5 years preceding July 1, 1966, and~~

~~B)~~ ~~The technologist has had at least 10 years of pertinent clinical laboratory experience prior to July 1, 1966, provided, that a minimum of 30 semester hours of credit toward a bachelor's degree from an accredited institution with a chemical, physical, or biological science as his major subject, or 30 semester hours in a school of medical technology approved in accordance with subsection (a)(2) shall reduce the required years of experience by 2 years, with any additional hours further reducing the required years of experience at the rate of 15 hours for 1 year.~~

~~2) An individual who has successfully passed the United States Public Health Service exam in order to qualify under Medicare and Medicaid as a clinical laboratory technologist will be considered to meet the qualifications for a medical technologist upon submission of documentation to the Department.~~

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.430 Cytotechnologist (Repealed)

~~An individual who meets one of the following qualifications shall qualify as a cytotechnologist. These qualifications must be documented on the Department's form entitled "Laboratory Personnel Qualifications Appraisal". (See Section 450.50(c)(3)):~~

~~a) The individual has successfully completed 2 years (60 semester hours of academic credit) in an accredited college or university with at least 12 semester hours in science, 8 hours of which are in biology, and has had 12 months of training in a school of cytotechnology accredited by one of the agencies recognized by the U.S. Commissioner of Education; or~~

~~b) The individual has successfully completed 2 years (60 semester hours of academic credit) in an accredited college or university with at least 12 semester hours in science, 8 hours of which are in biology, and has received 6 months of formal training in a school or agency cytotechnology accredited by one of the accrediting recognized by the U.S. Commissioner of Education and 6 months of full/time experience in cytotechnology in a laboratory affiliated with the school of cytotechnology; or~~

~~c) Prior to January 1, 1969, the individual has~~

~~1) graduated from high school~~

~~2) completed 6 months of training in cytotechnology in a laboratory directed by a physician certified or determined board eligible by the American Board of Pathology in pathologic anatomy and~~

~~3) completed 2 years of full time supervised experience in cytotechnology.~~

(Source: Repealed at 44 Ill. Reg. _____, effective _____)

Section 450.440 Technician (Repealed)

~~An individual who meets one of the following qualifications shall qualify as a technician: These~~

~~qualifications must be documented on the Department's form entitled "Laboratory Personnel Qualifications Appraisal". (See Section 450.50(c)(3)). Persons employed by a laboratory which meets the definition of a Class II Laboratory which do not presently have the minimum qualifications of a technician may continue to be employed by the laboratory in question until July 1, 1992 without meeting the requirements of a technician. After July 1, 1992, all technical persons performing laboratory testing must meet the qualifications set forth in this Part.~~

~~a)~~ ~~Successful completion of 60 semester hours of academic credit including chemistry and biology as well as a structured curriculum in medical laboratory techniques at an accredited institution or has an associate degree based on a course of study including those subjects from an accredited institution; or~~

~~b)~~ ~~High school graduate or equivalent and has completed at least 1 year in a technician training program in a school accredited by an accrediting agency approved by the U.S. Office of Education; or~~

~~c)~~ ~~High school graduate or equivalent and has successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).~~

(Source: Repealed at 44 Ill. Reg. _____, effective _____)

Section 450.450 Laboratory Assistant (Repealed)

~~A laboratory assistant is an individual who is employed in a laboratory and meets the education and experience requirements set forth by that laboratory director and who functions only under the direct supervision of a director, supervisor or technologist. These requirements must be established in writing and submitted to the Department with the Department's form entitled "Laboratory Personnel Qualifications Appraisal" (See Section 450.50(c)(3)).~~

(Source: Repealed at 44 Ill. Reg. _____, effective _____)

Section 450.460 Technical Supervisor

In a licensed (certified) laboratory, the technical supervisor shall be accessible to the laboratory to provide on-site, telephone or electronic consultation, and shall meet one or more specific option qualification requirements under each specialty or subspecialty of service in 42 CFR 493, Subpart M.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 450.470 Clinical Consultant

A clinical consultant candidate shall meet one or more of the options in 42 CFR 493, Subpart M.

(Source: Added at 44 Ill. Reg. _____, effective _____)

SUBPART F: OUT OF STATE LABORATORIES

Section 450.610 Criteria for Licensure

Clinical laboratories located outside of Illinois shall be certified, under CLIA Law, or that state's laboratory program, before accepting specimens referred by clinical laboratories located in Illinois.

~~a) Illinois licensure is required if clinical laboratories located outside of this state accept specimens referred by clinical laboratories located in Illinois.~~

~~b) Out-of-state laboratories shall:~~

~~1) Apply for an Illinois license in the same manner as facilities located in this State and pay the same licensee fees.~~

~~2) Comply with all standards applicable to laboratories located in Illinois. In cases in which the standards of practice permitted in the state in which the laboratory is located are not in accordance with these standards, the out-of-state laboratories shall comply with these Illinois standards when serving licensed physicians, dentists, hospitals, blood banks, or clinical laboratories located in Illinois which are required to have a license or permit.~~

~~3) Submit such reports as may be required, including but not limited to periodic reports of Illinois laboratories or blood banks referring specimens to the out-of-state laboratory.~~

~~4) Accept evaluation specimens referred by the Illinois Department of Public Health or participate in evaluation of specimens in programs approved by the Department.~~

~~5) If located in a state which licenses clinical laboratories, must hold a currently valid state license.~~

~~6) Submit with each state license application, a copy of the laboratory's current license to conduct interstate laboratory services under the Federal Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578, effective October 31, 1988). Such license shall be used by the Department~~

~~to determine compliance with this Act.~~

(Source: Amended at 44 Ill. Reg. _____, effective _____)

SUBPART G: PROFICIENCY SURVEY PROGRAM AND INSPECTION OF FACILITIES

Section 450.710 Inspections

a) All clinical laboratories required to be certified under CLIA Law~~have a license or permit~~ shall be open to inspection by representatives of the Department at all reasonable times. ~~The premises and operation of all clinical laboratories shall be inspected to study and evaluate the effect of the location, operation, supervision and procedures of such facilities on the health and safety of the people of this state. These inspections will be made at such time as may from time to time be determined by the Department, and may be announced or unannounced. These inspections may include on site review of records and reports pertaining to the technical operations of the laboratory.~~

b) The Department may submit forms, such as check lists, to be completed by the director of the laboratory in advance of inspection. ~~These forms may include questions relating to the construction, sanitation, equipment, procedures, and records which will be reviewed by the Department and will assist it in making inspections to determine compliance with the Act and this Part.~~

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.720 Proficiency Survey Program

Each laboratory shall enroll in a proficiency testing (PT) program that meets the criteria of 42 CFR 493, Subparts H, I, K and R. The laboratory shall enroll in an approved program or programs for each of the non-waived specialties and subspecialties for which it seeks certification, and shall test the samples in the same manner as patients' specimens.

~~a)~~ ~~The Department shall require the "demonstration of proficiency" in the performance of each test offered by licensed or permitted clinical laboratories by means of State-operated or State-approved proficiency testing programs. The Department may exclude some specific tests from this requirement.~~

~~b)~~ ~~Requirements for Testing Service Approval~~

~~1)~~ ~~The State-approved proficiency testing service must cover all clinical laboratory and anatomical pathology specialties and subspecialties in~~

~~which the laboratory performs tests as they are made available and are proven feasible for proficiency testing. One or more proficiency testing programs can be utilized to address all tests conducted by a laboratory.~~

~~2)~~ ~~The approved proficiency testing service must provide to the Department an annual list of subscribers among Illinois laboratories authorizing the proficiency testing service to report their proficiency test results to the Department.~~

~~3)~~ ~~The approved proficiency testing service must supply exception reports (cumulative survey management reports-cumulative deviancy reports) covering at least the immediately previous two years of testing and documenting the unsatisfactory results during that minimum two-year period. This report must be continuously updated with each new testing period and must be made available to both the participating laboratory and to the Department after each testing period.~~

~~4)~~ ~~The approved proficiency testing service must provide at least the following statistical parameters: mean or median, standard deviation or coefficient of variation, and some discussion and/or indication of accuracy and precision.~~

~~5)~~ ~~The approved proficiency testing service must document, in writing, the bases for establishing acceptable limits of performance. This documentation must be supplied to the Department and to each participating laboratory at least annually and must cover each test for which proficiency testing is provided. The yearly revision must include all changes made in the criteria for acceptable performance which are to prevail for the ensuing year.~~

~~c)~~ ~~A list of the State-approved proficiency testing programs may be obtained from the Department.~~

~~d)~~ ~~The costs of such State-approved proficiency testing shall be borne by the laboratory.~~

~~e)~~ ~~The laboratory shall keep on file a copy of the results of proficiency testing for review by the State laboratory evaluator.~~

~~f)~~ ~~Requirements for Laboratory Testing~~

~~1)~~ ~~The participating laboratory must test applicable materials each time they are distributed by the approved proficiency testing service according to a~~

schedule approved by the Department.

2) Those procedures performed by the laboratory for which test materials are provided by the approved proficiency testing service and which are not excluded by the Department from the "demonstration of proficiency" requirement must be proficiency tested by the participating laboratory each time test materials are received.

3) The participating laboratory must authorize the approved proficiency testing service to report proficiency test results to the Department.

4) The participating laboratory must test applicable materials only in the laboratory to which the license and the proficiency testing requirement applies using personnel and equipment used in that facility in providing services.

5) A laboratory shall be required to discontinue providing a service in a procedure or category of procedures (hematology, chemistry, bacteriology-mycology, parasitology, immunology-serology, immunohematology, etc.) if:

A) For three consecutive testing periods the laboratory fails to report on test materials received for procedures for which the laboratory is required to be proficiency tested; or

B) For three consecutive testing periods the laboratory demonstrates unsatisfactory performance in a procedure or category of procedures. A determination of satisfactory performance for a procedure for a testing period shall be based upon all results being within acceptable limits established by the proficiency testing service for that procedure and approved by the Department. A determination of satisfactory performance for a category of procedures shall be based upon 75% or more of the results in that category over three consecutive testing periods being within acceptable limits established by the Department.

6) A laboratory whose services have been disapproved because of unsatisfactory performance shall be reapproved by the Department to provide these services after meeting one of the following conditions, provided that proficiency testing is the only problem preventing reapproval.

A) The laboratory results for an unsatisfactory discontinued procedure

~~shall be within acceptable limits established by the proficiency testing service for two consecutive testing periods subsequent to the testing periods which resulted in the discontinuance of the procedure. The laboratory results for a disapproved category of procedures shall have 75% or more of the results within acceptable limits established by the proficiency testing service for two consecutive testing periods subsequent to the testing periods which resulted in discontinuance of the category of procedures.~~

~~B)~~ ~~On-site Testing~~

~~i)~~ ~~The laboratory director may request the Department to provide proficiency testing specimens for purposes of retesting. The cost of such proficiency testing specimens shall be borne wholly by the laboratory. The Department shall ship or cause to be shipped, hand carry or otherwise convey to the laboratory such proficiency testing specimens within three weeks after receipt of such request. The Department shall provide an on site visit by a laboratory evaluator for the purpose of determining deficiency correction.~~

~~ii)~~ ~~Successful analysis (100% of specific analysis or 75% of the results of a category are within acceptable limits as established by the testing service) shall be based upon test results of specimens similar in number and purpose to those normally received by the laboratory where performance has been judged unsatisfactory.~~

~~iii)~~ ~~Successful analysis and site visit findings shall be used to reapprove either a category of procedures or a given procedure.~~

~~g)~~ ~~Renewal of a license or permit may be denied for failure to maintain an acceptable standard of proficiency in the program and services provided by a laboratory.~~

(Source: Amended at 44 Ill. Reg. _____, effective _____)

SUBPART H: SPECIAL REQUIREMENTS PERTAINING TO BLOOD BANKS ~~(Repealed)~~

Section 450.810 General ~~(Repealed)~~

Blood banks operating in Illinois shall be licensed by the FDA under 21 CFR 600, 601, 606, 607, 610, 630 and 640.

(Source: Former Section repealed at 13 Ill. Reg. 11573, effective September 1, 1989; new Section added at 44 Ill. Reg. _____, effective _____)

SUBPART J: RECORDS AND REPORTS

Section 450.1010 Necessary Records

a) Complete records in regard to each specimen examined shall be kept on file in the laboratory for not less than five years. The~~Such~~ records shall contain:

1) Laboratory number or other identification of the specimen.

2) The name of the person from whom the specimen was taken, except in cases of anonymous HIV testing or of anonymous or coded premarital syphilis testing. The names and addresses of persons who have chosen to have HIV testing done anonymously may not be recorded in the files, except that any existing records referring to testing done before anonymity was chosen may be retained without linkage to the anonymous testing.

3) The name of the licensed physician or other authorized person, clinical laboratory, or blood bank submitting the specimen.

4) The date the specimen was collected and the date the specimen was received in the laboratory.

5) When a specimen is forwarded to another clinical laboratory for tests, the name, the date when the specimen was forwarded to the~~such~~ laboratory, the date it was tested, and the date the report of the findings of the test was received from the~~such~~ laboratory.

6) In case the specimen is an unsatisfactory specimen, the condition of the specimen when received.

7) The types and numbers of tests performed annually.

8) The results of the test conducted by the laboratory, the method used, the signature of the examiner.

9) *Clinical laboratory test results may be reported or transmitted to*:~~Results~~

~~of laboratory tests are to be reported to the referring laboratory and/or practitioner in accordance with Sections 3-101, 7-102, and 7-103 of the Act.~~

A) *The licensed physician*, the patient if requested, *or other authorized person who requested the test, their designee, or both;*

B) *Any health care provider who is providing treatment to the patient*; or

C) *An electronic health information exchange for the purposes of transmitting, using, or disclosing clinical laboratory test results in any manner required or permitted by HIPAA.*

10) *No interpretation, diagnosis, prognosis, or suggested treatment shall appear on the laboratory report form, except that a report made by a physician licensed to practice medicine in Illinois, a dentist licensed in Illinois, or an optometrist licensed in Illinois may include that information.*

11) *Nothing in this* Part *prohibits the sharing of information as authorized in Section 2.1 of the Department of Public Health Act.* (Section 7-102 of the Act)

b) Reports to be submitted to the Department.
A laboratory shall submit reports containing ~~such~~ information and data concerning its technical operations, as may be requested by the Department. These~~The Department may require that such~~ reports shall be notarized and signed by the owner and director of the laboratory~~, if these are different~~.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

SUBPART K: QUALITY CONTROL

Section 450.1150 Quality Control System Methodologies

a) Hematology

1) Manual Procedures

A) Each procedure shall be checked or recalibrated each day of use with standards (calibrators) or reference materials covering the range of expected values. See Section 450.520 for checking

dilutors and samplers.

B) Hemoglobin – methodology shall be calibrated monthly with standards that cover at least three concentrations and a zero point.

C) Hematocrit – Optimum packing time of microhematocrit centrifuges shall be determined before being placed into use and after major adjustments or repairs. The speed of the microhematocrit centrifuge shall be checked monthly. Tolerance limits shall be established. Timer checks shall be performed monthly. Tolerance limits shall be established.

D) Red and White cell counts – The hemocytometer counting chamber and coverslip shall be maintained in a condition that does not interfere with cell recognition or the volume of the chamber. Coverslips certified by the Bureau of Biological Standards shall be used. Counts shall be performed with certified pipettes or pipettors whose accuracy has been determined by the manufacturer.

E) Platelet counts – Manual platelet counts shall be performed by counting both sides of the chamber. Tolerance limits shall be established. A procedure to compare platelet results with the differential blood film shall be established.

F) Differential Leukocyte count – Blood smears shall be prepared and stained by a method which produces smears in which morphologic cell features can be evaluated. Cellular morphology shall be examined and platelets estimated routinely with the differential count.

2) Automated Procedures

A) Particle Counting and Hemoglobin

i) Calibration techniques shall follow the manufacturer's specifications.

ii) The director shall establish criteria for high and low counts and determine the policy for verification. Tolerance limits shall be established for duplicate testing.

iii) Background counts shall be performed daily on diluent and lysing agents.

iv) Reference materials shall be used each, or after each run to assess precision.

v) Each procedure shall be checked or recalibrated each 8 hours, if the instrument is used during the 8 hour period, with standards (calibrators) or reference materials covering the range of expected values.

B) Differential counts

i) The manufacturer's specifications shall be followed with respect to operation, calibration, and the use of reference materials.

ii) The director shall establish a policy for the review of all abnormal differentials that indicate an abnormal cellular, morphology or abnormal platelet enumeration.

3) Coagulation studies

A) Two levels of reference materials for prothrombin and or partial thromboplastin times shall be used during each 8 hours when the instrument is used, Action limits shall be established.

B) If available commercially, two levels of reference materials shall be included in each run for all other coagulation procedures. Patient specimens shall be performed in duplicate and tolerance limits established.

b) Chemistry

See Section 450.1120 for general quality control requirements. See Section 450.520 for checking dilutors and samplers.

1) Manual-Automated procedures which use a Spectrophotometer or Photometer

A) Calibration of the optical component of each instrument shall be done in accordance with the instrument manufacturer's instructions.

B) Each procedure shall be recalibrated at least every three months or more frequently in accordance with the following:

i) Procedures which are linear shall include at least 3 standard concentrations (calibrator) (unless the instrument manufacturer specifies that 3 calibrators are not necessary to determine procedure in linearity and calibration over the reportable range) including one at the highest level of the reportable range and one near the threshold (cutoff).

ii) Procedures which are non-linear over the reportable range shall include (unless the instrument manufacturer specifies that procedure calibration over the reportable range can be accomplished in another manner) a minimum of 5 standard concentrations (calibrator).

iii) The procedure is recalibrated when major instrument maintenance has been performed.

iv) The procedure is recalibrated in accordance with the manufacturer's recommendations and when a reagent lot number is changed.

v) The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits.

C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte.

2) Atomic Absorption Flame Photometers

A) The atomization rate shall be checked each day of use.

B) Each run of unknown specimens shall include two levels of reference materials.

C) Calibration and operation techniques shall follow the manufacturer's specifications.

D) Each procedure shall be recalibrated each day of use.

3) Chromatography

A) A standard (calibrator) shall be included with each batch of unknown specimens.

B) Calibration and operation techniques shall follow the manufacturer's specifications.

C) Reference materials (spiked samples) shall be included in each batch of unknown specimens and are treated the same as unknowns.

4) Electrophoresis

A) The linearity of a densitometer shall be checked each day of use.

B) Reference materials for comparison of migration patterns and stain intensity shall be included with each run.

5) Ion Selective Electrode

A) The manufacturer's recommendations shall be followed with respect to calibration and control procedures.

B) Reference materials shall be included with each run.

6) Radioimmunoassay

A) The stability of radioisotope counting equipment shall be checked each day of use with an appropriate radioactive reference source. Tolerance limits shall be established.

B) Background counts shall be performed each day of use and tolerance limits established.

C) Each procedure shall include calibrators (standards) as recommended by the reagent manufacturer.

D) Reference materials shall be included with each run.

E) The duration of the counting times shall follow the

recommendations of the instrument manufacturer.

7) Mass Spectrometry

A) Mass spectrometers shall be tuned daily.

B) Procedures for checking air leaks and determining ion ratios shall be available and followed.

C) Ion ratios shall be determined for each instrument and each assay if appropriate for the instrument.

D) If ion ranges are used, criteria shall be available for designating a positive.

c) Urinalysis

1) Specific gravity equipment shall be calibrated with distilled water and one other solution of known refractive index each day of use.

2) Screening or qualitative chemical urinalysis shall be checked daily by use of suitable reference materials.

3) Calibration and the use of reference materials for equipment which utilizes automatic readers shall follow the recommendations of the manufacturer.

d) Bacteriology-mycology

1) Each unit of media shall be properly labeled to indicate identity, date of preparation-receipt and expiration date.

2) Each batch of media shall be tested before use, or concurrently with selected organisms, for selectivity, sterility, enrichment, and biochemical response, ~~. A laboratory using commercially prepared microbiological culture media which is quality controlled in accordance with the National Committee for Clinical Laboratory Standards (NCCLS) "Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluid and Tissue", need not perform quality control checks for selectivity, enrichment and biochemical response provided that: the laboratory has documentation which may be provided through a media label or brochure that the quality control practices conform to NCCLS specifications: the laboratory documents receipt and condition of each batch of media to include sterility assessment by appropriate incubation and examination of~~

~~uninoculated media and notifies the media manufacturer of quality issues such as: cracked Petri plates, unequal filling of plates, cracked media in plates, hemolysis, freezing, excessive bubbles in media, contamination and sterility. Laboratories that prepare media for satellite laboratory locations must either perform the same quality control checks required of commercial and manufacturers (NCCLS Standards) and furnish documentation of media quality control checks to each location, or each laboratory must continue to perform media checks~~ as currently required under 42 CFR 493.1256(e)(4)~~42 CFR 405.1317 (b)(1)(1988). This exception does not apply to Campylobacter agar, chocolate agar, media for the selective isolation of pathogenic Neisseria, Mueller Hinton media and media used for the isolation of parasites, virus, mycoplasmas and Chlamydia~~.

3) Appropriate ATCC strains shall be available and maintained.

4) All reagents, strips, discs, and antisera shall be properly labeled as to lot number and expiration date and checked each day of testing with organisms that produce positive and negative reactions.

5) An adequate incubation system shall be used and shall~~must~~ be appropriate for the kinds of organisms isolated and volume of work. CO2 incubators shall be checked daily to insure that CO_2 concentration is maintained within established tolerance limits.

6) Flow charts may be used to indicate all steps to be employed to isolate and identify all organisms.

7) The daily log or worksheet shall reflect all tests and test results which lead to the isolation and identification of all microorganisms.

8) Staining materials shall be checked each day of use against organisms with the expected staining characteristics.

9) A wire loop used for quantitative tests shall be calibrated prior to placing into use and quarterly thereafter.

10) Agar Disc Diffusion methods:

A) The agar disc diffusion test shall be checked with each new batch of media and at least once each seven days with stock cultures of Escherichia coli ATCC 25922, Staphylococcus aureus ATCC 25923, and Pseudomonas aeruginosa ATCC 27853. Zone sizes

shall be recorded for each antimicrobial agent. Limits shall be established.

B) Petri dishes used shall have a diameter not less than 150 mm and contain no more than 12 discs.

C) Susceptibility tests shall be performed on pure cultures only.

D) A barium sulfate turbidity standard shall be used for the Kirby-Bauer method.

11) Minimum Inhibitory Concentration (MIC) Methods:

A) The MIC test shall~~must~~ be checked with each new batch of media and at least once each seven days with stock cultures of Escherichia coli ATCC 25922, Staphylococcus aureus ATCC 29213, and Pseudomonas aeruginosa ATCC 27853. The MIC values shall~~must~~ be recorded for each antimicrobial agent. Tolerance limits shall be established.

B) When trimethoprim-sulfamethoxazole is included in the battery of antibiotics, Streptococcus faecalis ATCC 29212 shall also be included as a control.

12) Automated susceptibility~~susceptability~~ testing systems shall follow the quality control requirements specified by the manufacturer or at a minimum those specified under item 11 above.

e) Parasitology

1) A calibrated ocular micrometer shall be available for determining the size of ova and parasites when size is a critical factor.

2) The laboratory shall have an atlas and~~and/or~~ reference collection of prepared slides, transparencies or gross specimens. The collection shall include organisms which the laboratory encounters and reports from patient specimens.

3) Permanent stains shall be used for the examination of intestinal~~intestional~~ protozoa and other parasites where internal structure is critical for proper identification.

4) Concentration methods shall be routinely employed on all stool specimens

negative for ova and parasites by direct examination methods. Concentration techniques shall be capable of detecting all cases of clinically significant parasites likely to be encountered in the community.

f) Immunology-Serology-Immunochemistry

Kits purchased for serological testing shall be used in accordance with the manufacturer's instructions.

1) VDRL/RPR

A) Non-reactive, minimally reactive, and reactive reference materials shall be included with each run.

B) The needle delivery shall be verified within plus or minus two drops per ml each time a new needle is used, when control patterns cannot be reproduced, and when the antigen does not drop clearly from the needle.

C) The revolutions per minute of the rotator shall be checked each week of use and be within the recommended tolerance limits.

D) Each new lot of antigen and reference materials shall be checked with non-reactive, weakly reactive and reactive reference materials before being placed into use.

E) Ambient temperature in the test area shall be maintained between 23 degrees Centigrade and 29 degrees Centigrade.

F) The antigen for VDRL testing shall be prepared fresh each day of use.

2) Qualitative tests

Positive and negative controls shall be included in each run. Each new lot of reagents and reference materials shall be parallel checked with one of known reactivity before being placed into use.

3) Quantitative tests

Each quantitative test shall include with each run a negative control, where applicable, a positive control of known titer or controls of graded reactivity. Each new lot of reagents and reference materials shall be parallel checked with one of unknown reactivity before being placed into use.

g) Immunohematology

1) ABO grouping reagents and Rh typing sera shall conform to the requirements of licensure under 21 CFR 600-680. Any facility which produces their own products shall adhere to these same requirements.

2) All antisera, ABO reagent red cells, anti-human globulin (Coombs) shall be tested each day of use with a positive control.

3) Antibody screening reagent red cells shall be tested each day of use with at least one known antibody.

4) All antisera except ABO antisera shall be tested each day of use with a negative control.

5) The reagent manufacturer's protocol for testing shall be followed.

6) An autologous cell control is required when samples are being tested for Rh type. An autologous cell control is not required to accompany the Rh type when testing donor samples.

h) Histopathology

1) All special stains shall be controlled by use of positive tissues.

2) All tissue specimens shall be kept in a preservative until microscopic examination and diagnosis have been completed by the pathologist.

3) All stains shall be filtered prior to each day of use.

4) All tissue processing solutions shall be changed or rotated on a regularly scheduled basis.

5) The quality of stains shall be evaluated daily by the director and suboptimal stains corrected immediately.

6) All gross tissue specimens received shall~~must~~ be properly labeled and securely packaged so as to maintain absolute certainty of identification throughout processing, recording and storage.

7) Slides shall~~must~~ be identified with permanent labels and stored so they are readily accessible. Paraffin blocks shall~~must~~ be adequately identified, indexed, stored in a cool place and protected against damage by heat for at

least 2 years. Wet tissue specimens shall be retained until a diagnosis has been made. The slide and a copy of the report shall~~must~~ be filed for at least 10 years.

8) The laboratory shall request that the tissue request shall contain the name, birthdate, name of the surgeon, clinical information and the date of surgery.

i) Cytogenetics

1) Special Equipment

A) Incubators shall~~must~~ be on special emergency lines.

B) Laminar Flow Hoods shall~~must~~ be used ~~(Class II)~~.

C) Karyotyping facilities shall~~must~~ be available with the production of hard copies.

2) Culture Initiation of Specimens

A) At least two (2) containers for each patient

B) Maximum of 1% patient failure (i.e. failure to provide a report as defined in Section 450.1150(j)(3)), for blood, amniotic fluid and chorionic villus samples in a period not to exceed 30 calendar days. If in excess of 1%, the laboratory director shall~~must~~ contact the Department and stop performing the tests until the laboratory can demonstrate a patient failure rate of less than one percent.

C) For other tissues higher patient failure rates are acceptable.

i) Skin and products of conceptions: maximum of 20% failure in a period not to exceed 30 calendar days. If in excess of 20%, the laboratory director shall~~must~~ contact the Department and stop performing the tests until corrective action is demonstrated.

ii) Bone Marrow: maximum of 5-10% failure in a period not to exceed 30 calendar days. If in excess of 5-10%, the laboratory director shall~~must~~ contact the Department and stop performing the tests until corrective action is demonstrated.

3) Analysis and Interpretation

A) Counting Chromosomes

i) At least 11-20 metaphases from the two containers shall~~must~~ be counted for routine blood, amniotic fluid, skin, products of conception, and chorionic villus specimens.

ii) For the Fragile-X chromosome, a minimum of 100 metaphases is required before reporting a negative result. Control values for Fragile-X shall be maintained.

iii) If a clinically significant hypermodal metaphase or a structurally abnormal chromosome is detected, 20 additional cells (or 10 additional centers) in each of the two cultures shall~~must~~ be analyzed.

iv) If 2 clinically significant hypomodal metaphases are detected, repeat steps in subsection (3)(A)(iii).

B) Karyotypes

i) A 400 band resolution is minimum.

ii) At least two ~~(2)~~ banded karyotypes (hard copies) shall~~must~~ be prepared for routine bloods, amniotic fluids, chorionic villus specimens, skins, and products of conception.

iii) For bone marrows, at least 25 metaphases shall~~must~~ be photographed and analyzed. A minimum of 20 cells shall be analyzed for the presence of the Philadelphia chromosome and other markers for chronic myelogenous leukemia.

C) Reporting and Interpretation

i) All reports shall~~must~~ adhere to the current International System of Cytogenetic Nomenclature.

ii) All abnormal findings should be accompanied by a recommendation to consult a Geneticist.

D) Documentation
In addition to other documentation required for any laboratory, documentation of power failure, failure rate, contamination, labeling discrepancy, poor or no growth, poor slide quality, interpretive dilemmas, and diagnostic errors shall be maintained.

4) Archives
Retention of adequate slides, films, hard copies and reports in order to re-analyze any cases challenged, shall be in accordance with the State statute of limitations.

j) Toxicology – Controlled Substances (Drugs of Abuse)
Laboratories which perform tests for controlled substances shall meet all pertinent requirements of the Act and regulations. In addition, the following items shall apply to toxicology laboratories.

1) The laboratory shall demonstrate proficiency as required under Section 450.720, except, the laboratory shall~~must~~ discontinue providing confirmatory testing if for two consecutive testing periods the laboratory either fails to report results for confirmatory testing or for two consecutive testing periods the laboratory fails to confirm the presence of any substance in any proficiency testing specimen or on one occasion falsely confirms and reports the presence of substances~~a substance(s)~~ not in the test specimen. Reinstatement to offer confirmatory testing shall require errorless performance in two subsequent proficiency testing surveys.

2) The director shall provide ~~in house~~ confirmatory testing of specimens whenever initial screening shows the presence of controlled substances. The confirmatory testing shall use different principles of chemistry and be at least as sensitive as the testing used for screening purposes. Drug screening may be performed on-site with confirmatory testing at a licensed laboratory or licensed toxicology laboratory~~Class II Permit as authorized under Section 2-109 of the Act, Licensed Laboratory, or Licensed Toxicology Laboratory~~.

~~3) The director shall develop a written program to maintain control and accountability from receipt of specimens until results are reported. In addition to other requirements of Section 450.140, requirements for segregation of these samples from other specimens received in the laboratory and the process for checking specimens for adulteration upon receipt in the laboratory, shall be stated.~~

34) Reports from the laboratory shall include limits of detection (LOD) for methods utilized and identify the method used to confirm positive screening results. Only specimens confirmed positive shall be reported positive for a specific drug or metabolites.

45) Each analytical run of specimens shall have at least three reference specimens including: a specimen containing no drug or metabolites; a specimen with a known amount of standard at or near the threshold (cutoff), and one additional reference specimen. Documentation that currently used methodology does not allow carryover to contaminate the testing of a subject's specimen, shall be maintained. A minimum of 10 percent of all test samples analyzed per batch shall be a mixture of reference specimens indicated in this subsection (j)(4)~~above~~.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

SUBPART M: HEALTH SCREENING

Section 450.1300 Health Screening and Approved Health Screening Tests

a) *All health screenings* shall *be conducted under a protocol approved by a physician licensed to practice medicine in all its branches that includes, but is not limited to, provisions concerning disclosure of the purpose and limitations of the screening tests to test subjects, proper collection of samples, and administration of tests, including staffing, staff training and equipment monitoring, adequate procedures for protecting the confidentiality of test subjects and test results, and appropriate referrals for medical attention.* ~~*"Health Screening" means the performance of any of the following tests for the purpose of assessing a phase of the general state of health of human subjects*~~ (Section 2-120(a)~~2-102.1~~ of the Act)~~:~~

~~1) Blood total cholesterol testing by finger stick method, and~~

~~2) Blood glucose testing by finger stick method.~~

b) *Health screening protocols* in this Part *shall be exempt from the provisions of Sections 7-101 and 7-102 of the Act.* (Section 2-120(b) of the Act)~~Health screening activities may only be conducted by the following entities:~~

~~1) *Laboratories which only perform health screenings on a not-for-profit or free-of-charge basis. Not-for-profit or free-of-charge basis* means screenings performed for a fee calculated to recover the actual cost of the test material and equipment and direct labor costs, excluding any cost

~~associated with test interpretation or other administrative costs or with no direct cost to the recipient;~~

~~2)~~ ~~*Licensed or permitted laboratories*; and~~

~~3)~~ ~~Licensed Hospital laboratories which are exempt from regulation under the Act and not precluded from such activities under the Hospital Licensing Act. (Section 2-102.1(a)(3) and (b) of the Act)~~

~~e)~~ ~~*Any entities which conduct more than one health screening event per* calendar *year shall file established protocols with the Department in accordance with the* provisions of this Subpart. A health screening event, as used in this Section, shall mean any day or continuous series of days not exceeding five on which health screening activities are conducted in the same location other than the principal location of the laboratory such as a health fair. Tests listed as health screening tests may be conducted at the principal location of the laboratory without the protocol required by this Subpart. (Section 2-102.1(a)(2) of the Act). Class III permit laboratories must submit a protocol regardless of where the health screening is conducted.~~

c~~d~~) ~~AGENCY NOTE:~~ Health screening tests shall~~should~~ not be used as diagnostic tests.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.1310 Protocol for Conducting Health Screening

a) Any entity that~~which~~ performs health screening shall establish a protocol for health screening activities that~~which~~ is *approved by a physician licensed to practice medicine in all its branches.* (Section 2-120(a) of the Act)~~(Section 2-102.1(a)(1) of the Act)~~

b) The protocol for conducting the health screening shall:

1) Indicate~~indicate~~ the tests~~test(s)~~ to be conducted;

2) Indicate~~indicate~~ the way in which results shall be reported to the test subject, including any available oral counseling and health professional referral program;

3) Indicate~~indicate~~ how confidentiality will be maintained with provisions that~~which~~ allow testing personnel, test subject, and test subject's representative access to the test results;

4) Include~~include~~ a written quality control program to ensure~~assure~~ accurate and precise test values as set by the physician signing the protocol and a description of the steps to be taken if the control values fall outside acceptable limits as set by the physician in the written quality control program;

5) Include~~include~~ the step-by-step instructions for the following:

A) Specimen~~specimen~~ collection, handling, transport, storage and disposal;

B) Patient~~patient~~ preparation;

C) Type~~type~~ and volume of specimen needed and the established rejection criteria;

D) Proper~~proper~~ specimen identification;

E) Proper~~proper~~ reagent use, such as labeling, proper lot number usage, expiration dates, and storage requirements;~~,~~ and

F) Instrument~~instrument~~ operation and calibration in accordance with the manufacturer's instructions;~~.~~

~~6) include a detailed procedure for all quantitative methodologies, to be performed at least once each twenty-four hours, to determine method linearity over the reportable range of valves for each analyte and instrument;~~

6~~7~~) Include~~include~~ directions for the use of one reference material and one calibrator or two reference materials with different concentrations once each 24 hour period in which the analyzer is used;

7~~8~~) Include~~include~~ a description of the training required of all staff conducting specific health screening tests;

8~~9~~) Include~~include~~ a copy of educational materials for each individual screening test given to each test subject;

9~~10~~) Be~~be~~ available to all health screening personnel at the test site;

10~~11~~) Be~~be~~ sent to the Department at least 30 days prior to the initial testing date

if more than one health screening event is conducted by that entity in a calendar year. These~~Such~~ protocols shall~~will~~ be effective for one year. An existing protocol may be renewed by submitting to the Department a letter from the physician who signed the protocol specifying that no changes have been made in the protocol and that the protocol will be used for health screenings over the next year. This letter shall~~must~~ be submitted within 30 days prior to the expiration of the existing protocol;

11~~12~~) Be~~be~~ signed, dated, and approved by a physician licensed to practice medicine in all its branches no earlier than three months prior to submission date;

~~13)~~ ~~include, for not-for-profit or free-of-charge operations, a statement from the physician who signs the protocol that the education and experience of the staff members are adequate to assure proper specimen collection, specimen handling, instrument operation, quality assurance, record-keeping, reporting of results, and proper sanitary conditions to protect the test subjects and the environment;~~

12~~14~~) Include~~include~~ a copy of the document to be given to each test subject which discloses the purpose and limitations of each individual screening test to be conducted;

~~15)~~ ~~state whether the testing to be conducted will be done on a *not-for-profit or free-of-charge basis* or for-profit basis. If the testing is conducted on a *not-for-profit basis*, then the calculations used to determine the actual cost of the test material and equipment must be included.~~

13~~16~~) Include~~include~~ copies of any forms used in the course of conducting health screening activities;

14~~17~~) Indicate~~indicate~~ how documentation and quality control items are traceable to each individual analyte and instruments used in the health screening process and how records shall be maintained; and

15~~18~~) Indicate~~indicate~~ how records of test subject results and documentation of quality control items shall be maintained for two years.~~, and~~

~~19)~~ ~~document the basis for any fee charged to the recipient indicating whether testing is being done on a for-profit or not-for-profit basis.~~

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.1320 Application for a Class III Permit to Conduct Health Screening (Repealed)

~~*The owner of a clinical laboratory which is operated and maintained exclusively for the purpose of conducting health screening tests by a person, corporation, organization, association or group which provides health screening services in accordance with Section 2-102.1* of the Act *either directly or indirectly on a for-profit basis must obtain a permit from the Department. Application shall be made on a form prescribed by the Department. The application shall be accompanied by an application fee of $200 for each such permit. The application shall be under oath* (i.e. signed by the owner or authorized officer and notarized)*, the permit shall expire* each year on a date specified on the permit*, and the application shall contain the following information:*~~

~~a)~~ ~~*The name and location of the owner's principal place of business;*~~

~~b)~~ ~~*The name of the owner of such facility and of the director thereof;*~~

~~c)~~ ~~When the owner is a corporation the names and addresses of all persons owning five percent or more of shares of the corporation;~~

~~d)~~ ~~a completed personnel form for the director(s), the anticipated schedule of hours for the director(s) to be at the laboratory during hours of testing, and other laboratories directed by the director(s);~~

~~e)~~ ~~*a description of the program and services provided by such clinical laboratory*;~~

~~f)~~ ~~The name of the laboratory assistant(s) or technician(s) employed and a completed personnel form for each laboratory assistant or technician;~~

~~g)~~ ~~the name of the person(s) who is in charge of the total laboratory operation at the test site and a personnel form(s) for that person;~~

~~h)~~ ~~a statement signed by the director indicating that the person in charge of the total laboratory operation at the test site has the education and training necessary to assure proper specimen collection, specimen handling, instrument operation, recordkeeping, reporting of results to assure confidentiality of test subjects and results, and proper sanitary conditions to protect the test subjects and environment;~~

~~i)~~ ~~an explanation of the location where all equipment and supplies are kept when not at the test site and the location where all records are kept relating to the laboratory operations at the test sites; and~~

~~j)~~ ~~a copy of the physician approved protocol.~~

(Source: Repealed at 44 Ill. Reg. _____, effective _____)

Section 450.1330 Reporting and Notification

a) All health screening entities shall file a protocol with the Department in accordance with Subpart M ~~of this Part~~.

b) All health screening entities shall notify the Department of all health screening sites, including street address, city, zip code and any other identifying data that are available, at least seven days prior to any health screening event.

c) All health screening entities shall notify the Department of all personnel anticipated to conduct any health screening event ~~including name, professions, training background, street address, city, zip code~~ at least seven days prior to any health screening event.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

Section 450.APPENDIX C Exempt, Permit, and License Requirements – An Overview (Repealed)

	EXEMPT	CLASS I PERMIT	CLASS II PERMIT	CLASS III PERMIT	HEALTH SCREENING (PROTOCOL)	LICENSE
ELIGIBILITY CRITERIA	Single practice medicine, podiatry, dentistry or local health authority or designated agency Single practice medicine includes: M.D.s, D.O.s D.C.s [See Section 450.5(b)(1)]	Single practice medicine, podiatry, dentistry or local health authority or designated agency Single practice medicine includes: M.D.s, D.O.s D.C.s [See Section 450.5(b)(2)]	Owner where lab operated exclusively for patients of physicians, podiatrists, or dentists who own or are employed by the owner or local health authority or designated agency or Class I [See Section 450.5(b)(3)]	Owner where lab operated exclusively for health screening for-profit basis either directly or indirectly [See Section 450.5(b)(4)]	Any laboratory [See Section 450.1300(b)]	Owner to operate lab to accept specimens from any persons authorized to submit such specimens [See Section 450.5(b)(5)]
DIRECTOR	None	M.D., D.O., D.D.S., D.P.M., D.C., Ph.D., M.S., or Grandfathered who meets regulations [See Section 450.210(b)(1)]	M.D., D.O., Ph.D., M.S., or Grandfathered who meets regulations [See Section 450.210(b)(2)]	M.D., D.O., Ph.D., M.S., or Grandfathered who meets regulations [See Section 450.210(b)(3)]	Non-profit testing no requirements except a protocol For-profit testing Class III permit	M.D., D.O., Ph.D., M.S., or Grandfathered who meets regulations [See Section 450.210(b)(4)]
PERSONNEL OTHER THAN DIRECTOR (Minimum)	None	Laboratory assistant, if any [See Section 450.210(b)(1)]	Technician or Technologist [See Section 450.210(b)(2)]	Technician or Laboratory Assistant [See Section 450.210(b)(3)]	None	General supervisor (if director not present full time) [See Section 450.210(b)(4)
FEES	None	Annual Initial $50 Renewal $25	Annual Initial $100 Renewal $50	Annual Initial $200 Renewal $100	None	Annual Initial $300 Renewal $150
INSPECTION FREQUENCY	No mandated inspection	No mandated inspection	At least every 2½ years	At least every 2 years	No mandated inspection	At least annually
PROFICIENCY TESTING	None	Required for tests offered [See Section 450.720]	Required for tests offered [See Section 450.720]	Required for tests offered [See Section 450.720]	None	Required for tests offered [See Section 450.720]
TEST PERMISSIBLE	List of minor tests [See Section 450.35(a)]	Minor and simple tests [See Section 450.35(b)]	Minor, simple and complex test [See Section 450.35(c)]	Cholesterol and glucose [See Sections 450.35(d) and 450.1300(a)]	Cholesterol and glucose [See Section 450.1300]	Any test as long as Director qualifies [See Section 450.35(e)]

2519 (Source: Repealed at 44 Ill. Reg. _____, effective _____)